

05-31-05

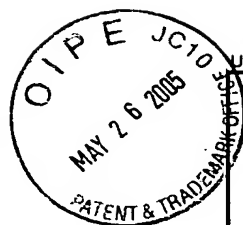
1FW

PTO/SB/21 (09-04)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.



TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

TRANSMITTAL FORM (to be used for all correspondence after initial filing)		Application Number	10/641376
		Filing Date	August 14, 2003
		First Named Inventor	Michael S. H. Chu
		Art Unit	3739
		Examiner Name	Not Yet Assigned
Total Number of Pages in This Submission	11	Attorney Docket Number	MIY-P01-027

ENCLOSURES (Check all that apply)

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Copy of references BA-BF and CA-CJ1 Return Receipt Postcard
Remarks		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	ROPES & GRAY LLP		
Signature			
Printed name	Erika Takeuchi		
Date	May 26, 2005	Reg. No.	55,661

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EV 619645415 US, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: May 26, 2005

Signature: Linda Blake (Linda Blake)

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EV 619645415 US, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: May 26, 2005

Signature: Linda Blake

(Linda Blake)

Docket No.: MIY-P01-027
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Chu et al.

Confirmation No.: 9640

Application No.: 10/641376

Art Unit: 3739

Filed: August 14, 2003

Examiner: Not Yet Assigned

For: SPACER FOR SLING DELIVERY SYSTEM

May 26, 2005

INFORMATION DISCLOSURE STATEMENT (IDS)

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

Applicants have become aware of the document, cited in an International Search Report issued January 16, 2004 during the prosecution of international application no. PCT/US03/25451, which corresponds to the above referenced application, and in accordance with 37 CFR 1.97(b)(2), (b)(3) and (e)(1), hereby submit(s) these documents for the Examiner's consideration. These documents are also cited on the enclosed PTO Form SB/08, and a copy of the International Search Report and each document cited thereon are enclosed as well.

This statement is not to be interpreted as a representation that the cited documents are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any document herein be construed *per se* as a representation that such document is prior art. Moreover, Applicants understand the Examiner will make an independent evaluation of the cited documents.

A copy of each reference on the PTO/SB/08 is attached, except the U.S. Patents.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 18-1945, under Order No. MIY-P01-027. A duplicate copy of this paper is enclosed.

Dated: May 26, 2005

Respectfully submitted,

By 

Erika Takeuchi

Registration No.: 55,661

Fish & Neave IP Group

ROPES & GRAY LLP

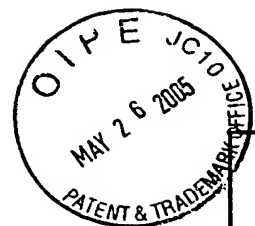
1251 Avenue of the Americas

New York, NY 10020-1104

(212) 596-9479

(212) 596-9090 (Fax)

Attorneys/Agents For Applicant



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO				Complete If Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Application Number	10/641376
				Filing Date	August 14, 2003
				First Named Inventor	Michael S. H. Chu
				Art Unit	3739
				Examiner Name	Not Yet Assigned
Sheet	1	of	5	Attorney Docket Number	MIY-P01-027

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	AA	US-5,250,033	10-05-1993	Evans et al.	
	AB	US-5,256,150	10-26-1993	Quiachon et al.	
	AC	US-5,368,595	11-29-1994	Lewis et al.	
	AD	US-5,456,722	10-10-1995	McCleod et al.	
	AE	US-5,540,703	07-30-1996	Barker et al.	
	AF	US-5,611,515	03-18-1997	Benderev et al.	
	AG	US-5,702,215	12-30-1997	Li	
	AH	US-5,742,943	04-28-1998	Chen	
	AI	US-5,840,011	11-24-1998	Landgrebe et al.	
	AJ	US-5,860,993	01-19-1999	Thompson et al.	
	AK	US-5,934,283	08-10-1999	Willem et al.	
	AL	US-5,935,122	08-10-1999	Fourkas et al.	
	AM	US-5,954,057	09-21-1000	Li	
	AN	US-6,042,534	03-28-2000	Gellman et al.	
	AO	US-6,099,547	08-08-2000	Gellman et al.	
	AP	US-6,264,676	07-24-2001	Gellman et al.	
	AQ	US-6,382,214	05-07-2002	Raz et al.	
	AR	US-6,478,727 B2	11-12-2002	Scetbon	
	AS	US-6,491,703 B1	12-10-2002	Ulmsten	
	AT	US-6,582,442	06-24-2003	Cabak et al.	
	AU	US-6,596,002	07-22-2003	Therin et al.	
	AV	US-6,612,977	09-02-2003	Staskin et al.	
	AW	US-6,638,210 B2	10-28-2003	Berger	
	AX	US-6,638,211	10-28-2003	Suslian et al.	
	AY	US-6,641,525 B2	11-04-2003	Rocheleau et al.	
	AZ	US-6,648,921 B2	11-18-2003	Anderson et al.	
	AA1	US-6,652,450 B2	11-25-2003	Neisz et al.	
	AB1	US-6,755,781	06-29-2004	Gellman	
	AC1	US-6,685,629	02-03-2004	Therin	
	AD1	US-6,802,807	11-12-2004	Anderson et al.	
	AE1	US-6,830,052	12-14-2004	Carter	
	AF1	US-2002/0072694 A1	06-13-2002	Snitkin et al.	
	AG1	US-2002/0077526	06-20-2002	Kammerer et al.	
	AH1	US-2002/0116025	08-22-2002	Haab	
	AI1	US-2002/0138025	09/26/2002	Gellman et al.	
	AJ1	US-2002/0147382	10-10-2002	Neisz et al.	
	AK1	US-2002/0151910	10-17-2002	Gellman et al.	
	AL1	US-2002/0161382 A1	10-31-2002	Neisz et al.	
	AM1	US-2003/0004580	01-02-2003	Sump et al.	
	AN1	US-2003/0010929	01-16-2003	Priewe et al.	
	AO1	US-2003/0023135 A1	01-30-2003	Ulmsten et al.	
	AP1	US-2003/0028075 A1	02-06-2003	Ulmsten et al.	
	AQ1	US-2003/0100954	05-29-2003	Schuldt-Hempe et al.	
	AR1	US-2003/0130670 A1	07-10-2003	Anderson et al.	
	AS1	US-2003/0171644	09-11-2003	Anderson et al.	
Examiner Signature				Date Considered	

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete If Known	
				Application Number	10/641376
				Filing Date	August 14, 2003
				First Named Inventor	Michael S. H. Chu
				Art Unit	3739
				Examiner Name	Not Yet Assigned
				Attorney Docket Number	MIY-P01-027
Sheet	2	of	5		

	AT1	US-2,917,878	12-22-1959	Edwin et al.	
	AU1	US-3,875,937	04-08-1975	Schmitt et al.	
	AV1	US-3,937,223	02-10-1976	Roth	
	AW1	US-5,507,754	04-16-1996	Green et al.	
	AX1	US-5,562,689	10-08-1996	Green et al.	
	AY1	US-5,639,274	06-17-1997	Fischell et al.	
	AZ1	US-5,700,286	12-23-1997	Tartaglia et al.	
	AA2	US-6,110,101	08-29-2000	Tihon, C. et al.	
	AB2	US-6,299,607	10-09-2001	Osborn, III et al.	
	AC2	US-2003-0009181-A1	01-09-2003	Gellman, B. et al.	
	AD2	US-2003-0045774-A1	03-06-2003	Staskin, D. et al.	
	AE2	US-2002-0091373	07-11-2002	Berger, Yitzhak	
	AF2	US-2002/0099258	07-25-2002	Staskin, D.R., et al.	
	AG2	US-2003/0065402	04-03-2003	Anderson, K.A. et al.	
	AH2	US-2002/015648	10-24-2002	Gellman, B. et al.	

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)					
	BA	DE 8203923		04-07-1983	Henkel KGAA		
	BB	WO 96/06567		03-07-1996	MedScand AB		
	BC	WO-97/13465		04-17-1997	MedScand Medical AB		
	BD	WO-00/74633		12-14-2000	Ethicon, Inc.		
	BE	WO 02/28315		04-11-2002	American Med System		
	BF	DE-20204669		09-11-2003	Aesculap AG & Co.		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	CA	BAYER et al., "A New Approach to Primary Strengthening of Colostomy with Marlex® Mesh to Prevent Paracolostomy Hernia," Surgery, Gynecology & Obstetrics, December 1986, Vol. 163, pp. 579-580.	
	CB	DELORME., "La bandelette trans-obturatrice: un procede mini-invasif pour traiter l'incontinence urinaire d'effort de la femme," Progres en Urologie, Vol. 11, 2001, pp. 1306-1313. (English summary therein)	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete If Known	
				Application Number	10/641376
				Filing Date	August 14, 2003
				First Named Inventor	Michael S. H. Chu
				Art Unit	3739
				Examiner Name	Not Yet Assigned
				Attorney Docket Number	MIY-P01-027
Sheet	3	of	5		

	CC	FIANU et al., "Absorbable Polyglactin Mesh for Retropubic Sling Operations in Female Urinary Stress Incontinence," Gynecol. Obstet. Invest. Vol. 16, pp. 45-50 (1983).	
	CD	GIESY et al., "Ureteral Instrumentation: A New System for Continued Access via a Safety Guidewire," The Journal of Urology, No. 4, Part 2, April 1988, p. 282A.	
	CE	GITTES et al., No-Incision Pubovaginal Suspension for Stress Incontinence, Journal of Urology, vol. 138, Sep. 1987, pp. 568-570.	
	CF	HAAB et al. "Feasibility of Outpatient Percutaneous Bladder Neck Suspension Under Local Anesthesia," Urology, Vol 50, 1997, pp. 585-587.	
	CG	JACQUETIN, B., "Utilisation du TVT dans la chirurgie de l'incontinence urinaire féminine", J Gynecol Obste Biol Reprod 2000, Vol. 29, pp. 242-247. (English summary therein)	
	CH	KERSEY et al., "The Gauze Hammock Sling Operation in the Treatment of Stress Incontinence," British Journal of Obstetrics and Gynecology, Vol. 90, pp. 945-949, October 1983.	
	CI	KOVAC et al., "Pubic Bone Suburethral Stabilization Sling for Recurrent Urinary Incontinence," Obstetrics & Gynecology, April 1997, Vol. 89, No. 4, pp. 624-627.	
	CJ	NORRIS et al, "Use of Synthetic Material in Sling Surgery: A Minimally Invasive Approach," Journal of Endourology, Vol. 10, No.3, June 1996.	
	CK	PETROS, P., "An Integral Theory of Bladder Neck Opening, Closure and Urinary Incontinence in the Female", International Journal of Gynecology & Obstetrics, XXIII World Congress of Gynaecology and Obstetrics (FIGO) 1991.	
	CL	PETROS et al., "An Integral Theory and Its Method for the Diagnosis and Management of Female Urinary Incontinence," Scandinavian Journal of Urology and Nephrology, Supplement 153, 1993, pp. 1-93.	
	CM	PETROS, "Ambulatory Surgery for Urinary Incontinence and Vaginal Prolapse," The Medical Journal of Australia, July 1994, Vol. 161, pp. 171-172.	
	CN	PETROS et al., "Urethral Pressure Increase on Effort Originates From Within the Urethra, and Continence From Mulculovaginal Closure", Neurourology and Urodynamics, 1995, pp. 337-350.	
	CO	PETROS, "The Intravaginal Slingplasty Operation, a Minimally Invasive Technique for Cure of Urinary Incontinence in the Female," Aust. And N.Z. Journal of Obstetrics and Gynecology, 1996, Vol. 4, pp. 453-461.	
	CP	PETROS, "Medium-term Follow-up of the Intravaginal Slingplasty Operation Indicates Minimal Deterioration of Urinary Continence With Time", Aust. And N.Z. Journal of Obstetrics and Gynecology, 1999, Vol. 39, pp. 354-356.	
	CQ	RAZ, "Modified Bladder Neck Suspension for Female Stress incontinence," Urology, January 1981, Vol. 17, No. 1, pp. 82-85.	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/641376
				Filing Date	August 14, 2003
				First Named Inventor	Michael S. H. Chu
				Art Unit	3739
				Examiner Name	Not Yet Assigned
Sheet	4	of	5	Attorney Docket Number	MIY-P01-027

	CR	RAZ et al. "Fascial Sling to Correct Male Neurogenic Sphincter Incompetence: The McGuire/Raz Approach," The Journal of Urology, Vol. 139, 1988, pp. 528-531.	
	CS	RAZ et al. "Vaginal Wall Sling" The Journal of Urology, Vol. 141, No. 1, January 1989, pp. 43-46.	
	CT	STAMEY, "Endoscopic Suspension of the Vesical Neck for Urinary Incontinence," Surgery, Gynecology & Obstetrics, April 1973, Vol. 136, No. 4, pp. 547-554	
	CU	STAMEY, "Endoscopic Suspension of the Vesical Neck for Urinary Incontinence in Females," Ann. Surg., October 1980, Vol. 192, No. 4, pp. 465-471.	
	CV	STAMEY, "Endoscopic Suspension of the Vesical Neck," Stanton, Tanagho (eds). Surgery of Female Incontinence. Springer-Verlag, Berlin; 1986, pp. 115-132.	
	CW	STASKIN, "Sling Surgery for the Treatment of Female Stress Incontinence," Problems in Urology, Vol. 5, No. 1, March 1991, pp. 106-122.	
	CX	STASKIN et al., "The Gore-tex sling procedure for female sphincteric incontinence: indications, technique, and results," World Journal of Urology, Vol. 15, No. 5, 1997, pp. 295-299.	
	CY	SUSSMAN et al., "The Raz Bladder Neck Suspension: Five-Year Experience", The Journal of Urology, 1993, Vol. 145, p. 223A.	
	CZ	ULMSTEN et al., "Connective Tissue Factors in the Aetiology of Female Pelvic Disorders", Ann. Med., December 1990, Vol. 22, No. 6, p. 3.	
	CA1	ULMSTEN et al., "Surgery for Female Urinary Incontinence", Current Opinion in Obstetrics & Gynecology, 1992, Vol. 4, No. 3, pp. 456-462.	
	CB1	ULMSTEN, et al, "Intravaginal Slingplasty", Zentralblatt für Gynäkologie, 1994, pp. 398-404.	
	CC1	ULMSTEN et al., "Intravaginal Slingplasty (IVS): An Ambulatory Surgical Procedure for Treatment of Female Urinary Incontinence", Scandinavian Journal of Urology and Nephrology, March 1995, Vol. 29, No. 1, pp. 75-82.	
	CD1	ULMSTEN et al., "An Ambulatory Surgical Procedure Under Local Anesthesia for Treatment of Female Urinary Incontinence", The International Urogynecology Journal, 1996, pp. 81-86.	
	CE1	ULMSTEN et al., "A Multicenter Study of Tension-Free Vaginal Tape (TVT) for Surgical Treatment of Stress Urinary Incontinence", International Urogynecology Journal, 1998, Vol. 9, No. 4, pp. 210-213.	
	CF1	ULMSTEN et al., "A Three-Year Follow Up of Tension Free Vaginal Tape for Surgical Treatment of Female Stress Urinary Incontinence", British Journal of Obstetrics and Gynaecology, April 1999, Vol. 106, pp. 345-350.	
	CG1	ULMSTEN, U., "An Introduction to Tension-Free Vaginal Tape (TVT) – A New Surgical Procedure for Treatment of Female Urinary Incontinence", International Urogynecology Journal, 2001, Vol. 12, Suppl. 2, pp. S3-S4.	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

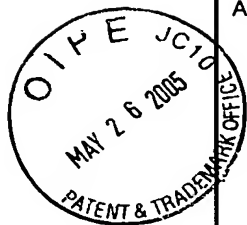
Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete If Known	
				Application Number	10/641376
				Filing Date	August 14, 2003
				First Named Inventor	Michael S. H. Chu
				Art Unit	3739
				Examiner Name	Not Yet Assigned
				Attorney Docket Number	MIY-P01-027
Sheet	5	of	5		

	CH1	ULMSTEN, U., "The Basic Understanding and Clinical Results of Tension-Free Vaginal Tape for Stress Urinary Incontinence", Der Urologe [A] 4-2001, pp. 269-273.	
	CJ1	Copy of International Search Report from International Application No. PCT/US03/25451 dated January 16, 2004	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--



Certificate of Express Mailing Under 37 CFR 1.10

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail, Airbill No. EV 619645415 US in an envelope addressed to:

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

on May 26, 2005
Date

Signature

Linda Blake

Typed or printed name of person signing Certificate

Registration Number, if applicable

212-596-9000

Telephone Number

Note: Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

IDS (Citation) by Applicant (SB/08) (5 pages)
Copy of references BA-BH and CA-CJ1 (41 references)
Return Receipt Postcard
This Certificate of Express Mailing under 37 CFR 1.10